Increased Detection Rates for HIV Infection Using Rapid HIV Testing at Publicly Funded Counseling and Testing Sites in New Jersey

Cadoff EM, Paul SM, Bruccoleri P, Jackson FN, Stralkus K, Holmquist N, Crayne-Pereira R, Bataille S, Nichol L, Williams R, Wolski M, Martin EG

UMDNJ Robert Wood Johnson Medical School
University of Medicine & Dentistry of New Jersey

New Jersey Department of Health and Senior Services

ABSTRACT

Background: New Jersey ranks fifth in the nation for the number of AIDS cases. In 2002, 1436 new casesof HIV infection were reported, with about one fourth detected through publicly funded counselling and testing (CTS) sites which perform 65,000 tests a year. It is estimated that one third of infections are undiagnosed and unreported. These estimated 700 unreported cases hinder efforts to control the spread of HIV.

Methods/Description: Recently, the FDA approved the OraQuick® Rapid HIV-1 Antibody test, but requires testing sites to have Quality Assurance programs. NJ also requires state licensure. In September, 2003 the NJ Dept of Health and Senior Services, Division of HIV/AIDS Services sought expertise in point-of-care-testing (POCT) in order to develop a statewide OraQuick® implementation plan.

Rapid on-site HIV testing shortens the time between initial contact and referral linkages, and strengthens HIV prevention and treatment efforts. It was anticipated that patterns and rates of positivity might change as clients learn that test results are available immediately. Early data from New Jersey's first 1,000 tests supports these expectations.

To pilot rapid testing within licensure regulations, testing was begun at CTS sites whose laboratory licenses could cover OraQuick® testing. Confirmatory testing for OraQuick® positives is done at one state laboratory. Rapid testing began at 1 site on November 1, 2003, with 3 others starting in early 2004.

Results: For clients tested with OraQuick® at pilot sites, the seropositive rate doubled to 4.72% from 2.36% one year earlier with traditional testing. Of the positive clients in the pilot, 63% were previously undiagnosed. Historically statewide, only about 1/3 of CTS positive results represent new cases.

Conclusions: This early data shows that the seropositive rate has increased at New Jersey's CTS centers with the introduction of OraQuick® rapid testing. It further shows that a greater percentage of the positive results are new diagnoses. This doubling of the positive rate, with a doubling of the new diagnosis rate among those positives, suggests that the OraQuick® testing may increase the yield of new HIV cases as much as four-fold. Whether this represents new populations of patients who were previously not being tested, or improved detection rates in previously targeted populations remains to be determined. These data reflect detection rates of HIV seropositivity, and do not assess the rate of new HIV infections.

INTRODUCTION

- New Jersey is a high prevalence state:
  - 5th in the US in cumulative reported AIDS cases,
  - 3rd in cumulative reported pediatric AIDS cases, and
  - 1st in the proportion of women with AIDS among its cumulative reported AIDS cases.[1]
- It is estimated that undiagnosed and unreported cases amount to approximately one third of all estimated infections, or about 700 unreported cases per year in New Jersey.
- In 2002, one fourth of new cases were detected through publicly funded counselling and testing (CTS) sites.
- Identification of new cases is important because:
  - More people learn their HIV status, and if infected can be referred for treatment, prevention programs, and social services much more rapidly.
  - People who know they are infected with HIV are more likely to practice risk-reduction, especially if a brief behavioral intervention is conducted at the patient visit.[2]
- Antibody testing to diagnose HIV was introduced in 1985.[3] The standard laboratory testing protocol for HIV requires obtaining a specimen and sending it to a licensed laboratory for testing. The patient needs to return for a second visit to receive test.
- In 2003, the U.S. Food and Drug Administration approved the OraQuick® Rapid HIV-1 Antibody test (OraSure Technologies, Inc., Bethlehem, PA) as the first CLIA 'waived' rapid HIV point-of-care test (POCT).
- Rapid diagnostic HIV testing has several clinical applications. These include
  - assisting in diagnosis and counseling of patients with HIV disease,
  - reducing vertical HIV transmission for women who present in labor with unknown HIV status, and
  - reducing the risk of occupational and non-occupational transmission of HIV.[4,5]
- With rapid testing, most people do not need to return to obtain their test results.
- Approximately 65,000 HIV tests are performed at publicly funded counseling and testing sites annually in New Jersey. In 2003,
  - only 65% of persons tested received their results,
  - 2.6% of persons tested had positive results, and
  - only 1/3 of positive results were newly diagnosed cases.
- The New Jersey Department of Health and Senior Services Division of HIV/AIDS Services (NJDHSS DHAS) introduced rapid HIV testing at selected publicly funded counseling and testing sites to improve the proportion of high risk persons tested for HIV and to increase the proportion of people who learn their test result.
- This poster presents preliminary findings of test result patterns after the introduction of rapid, point-of-care HIV testing at publicly funded CTS sites in New Jersey.

METHODS

- FDA approval of OraQuick® was linked to requirements that a testing site have a Quality Assurance program in place before offering OraQuick® testing. In the State of New Jersey, state licensure is also required, regardless of CLIA waiver.
- In September, 2003 the New Jersey Department of Health and Senior Services (NJDHSS), Division of HIV/AIDS (DHAS) and Robert Wood Johnson Medical School started to set up OraQuick® Rapid HIV testing at CTS sites statewide based on the RWJMS point-of-care testing program.
- To pilot rapid testing under New Jersey's licensure regulations, testing was begun at CTS sites whose existing laboratory licenses could easily be expanded to cover OraQuick® testing.
- A laboratory director was selected, QA plan developed, policies and procedure written, and laboratory licenses obtained prior to starting rapid testing at each site.
- Staff at the pilot CTS sites received counseling training and rapid testing training, completed competency testing, and passed proficiency testing prior to offering rapid HIV testing. All rapid testing sites were licensed by NJDHSS.
- All preliminary positive rapid tests were confirmed with a Western blot performed by the NJDHSS laboratory.
- Data was collected using the standard Centers for Disease Control and Prevention counseling and testing form, including data specific to rapid testing using the local fields. The forms were sent to NJDHSS and scanned into the counseling and testing database.
- Data analysis was done using SAS (version 8.02, SAS Institute, Cary, NC) and Microsoft Access (version 2000, Microsoft Corporation, Redmond, WA)

RESULTS

- Rapid testing began at 1 site (RWJ) on November 1, 2003, with 3 other sites (JCMC, Mon, and BI) starting in the first quarter of 2004.
- Preliminary data from the first 1000 clients tested with rapid testing revealed:
  - 99.9% of clients received their test results,
  - the seropositive rate increased to 4.7%, and
  - 63% of positives were in previously undiagnosed patients.
- Figure 1 compares the seropositive rate for each site, compared to the same months one year earlier when rapid testing was not available.

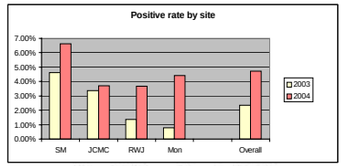

Figure 1. Seropositive rate by site

- By the end of the first year, rapid testing was available at more than 50 sites. For all sites for the first year:
  - 10429 rapid tests were done,
  - over 99.7% of clients received their test results,
  - 268 (2.5%) were positive
  - 159 of the positives (59%) were newly positive
  - 4 positive OraQuick® results (0.04%) were negative on confirmatory testing
- Data from the different time periods are compared in the charts that follow. Data for the Prior Period and for the first 1000 tests reflect results only from the pilot sites. First Year data include sites that were not reflected in the Prior Period data, and include prenatal screening programs which historically have had lower positive rates.
- As seen in Figure 2, for clients tested at the pilot CTS sites using OraQuick® rapid testing, the seropositive rate was 4.72%. For the same period in the prior year, when OraQuick® rapid testing was not available, the seropositive rate was 2.36% (similar to the statewide rate of 2.6% in 2002). Among the sites in the OraQuick® pilot program, the seropositive rate doubled initially. The seropositive rate has subsequently returned to what was seen prior to the introduction of rapid testing.

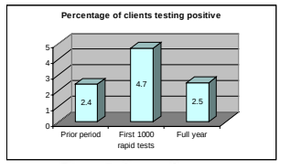

Figure 2. Seropositive rate

- Figure 3 demonstrates the increased percentage of positive results in previously undiagnosed patients. Of the positive results at the CTS pilot sites, approximately 63% were in previously undiagnosed patients. Historically statewide, only about 1/3 of CTS positive results represented new diagnoses. After a full year of rapid testing, the rate of new cases among the clients tested has remained higher than before rapid testing was available.

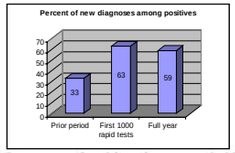

Figure 3. Percentage of positives that are newly identified

- Figure 4 shows that almost all clients receive their test results, compared to only 65% with conventional testing. This also compares favorably to 95% for confidential testing when clients paid for their test in advance using home blood collection kits.[6]

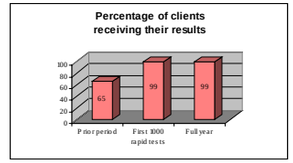

Figure 4. Percent of clients receiving their results

- Through the first year of testing, 4 of 10,429 tests (0.04%) were false positive rapid results. The confirmatory Western Blot testing was negative.

CONCLUSIONS

- Rapid HIV testing has been successfully implemented at publicly funded counseling and testing sites in New Jersey, with over 60 counselors performing testing at over 50 CTS sites..
- This early data suggested an increase in the seropositive rate at New Jersey's CTS centers with the introduction of OraQuick® rapid HIV testing. Later data suggests that the seropositive rate has not changed.
- Rapid testing identified more previously undiagnosed persons. About 60% of people who test positive were previously undiagnosed.
- The percentage of persons receiving post-test counseling and test results increased from 65% prior to rapid testing to 99.9% with rapid testing.
- A minimal number of persons tested had a false positive rapid test (0.04%).
- Based on the success of rapid testing thus far, New Jersey has begun to expand rapid testing to 179 publicly funded counseling and testing sites.

REFERENCES

1. Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report 2002. http://www.cdc.gov/hiv/stats/addendum.htm
2. Centers for Disease Control and Prevention. Incorporating HIV Prevention into the Medical Care of Persons Living with HIV: Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR 2003 July 18; 52(RR12):1-24.
3. Truong, H-H M and Klausenr JD. Diagnostic Assays for HIV-1 infection. MLO 2004;36 no. 7: 12-20.
4. Paul S, Grimes-Dennis J, Burr C, and DiFerdinando GT. Rapid Diagnostic Testing for HIV: Clinical Implications. 2003(Supplement);100:11-14.
5. Centers for Disease Control and Prevention. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. MMWR 2005:54(RR02):1-20.
6. PR Newswire. Confide® Results are Demonstrating Ease of Use and Public Health Benefits. www.aegis.com/news/pr/1997/PR970132.html.